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UMBILICAL CORD BLOOD STEM CELLS: MY BODY MAKES THEM, BUT DO I GET TO KEEP THEM? ANALYSIS OF THE FDA PROPOSED REGULATIONS AND THE IMPACT ON INDIVIDUAL CONSTITUTIONAL PROPERTY RIGHTS

I. FDA PROMULGATION OF REGULATIONS REGARDING CORD BLOOD STEM CELL BANKING

The Food and Drug Administration ("FDA") recently released a draft document¹ regarding the proposed regulation of the collection of umbilical cord blood stem cell² products.³ The structure of the proposed regulation was such that it was likely to prove to be an obstacle to parents of children dying of certain blood related illnesses.⁴ After much public concern and discussion, the FDA proposed a new regulatory framework⁵ that included regulatory oversight of cord blood stem cells at a regulatory level much less onerous for the industry, technology, and parents of chil-

1. FOOD AND DRUG ADMINISTRATION, DRAFT DOCUMENT CONCERNING THE REGULATION OF PLACENTAL/UMBILICAL CORD BLOOD STEM CELL PRODUCTS INTENDED FOR TRANSPLANTATION OR FURTHER MANUFACTURE INTO INJECTABLE PRODUCTS, [Dkt. No. 96N-0002], (Dec. 1995) [hereinafter CORD BLOOD DRAFT DOCUMENT].

2. Cord blood stem cells are the blood that remains in the umbilical cord and the placenta after birth. This blood was formerly discarded as waste. Today, however, the cord blood stem cells may be retrieved through a simple procedure that may be performed quickly by hospital personnel. *Cord Blood Collection Information* (visited Oct. 27, 1996) <<http://www.cordblood.com/collect.html>>.

3. The draft document defines "cord blood stem cell products" as "products containing hematopoietic progenitor cells derived from placental/umbilical cord blood to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries." CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 14.

4. Cord blood stem cell transplants may be useful in the treatment of diseases such as leukemia, AIDS, and certain autoimmune diseases including diabetes and rheumatoid arthritis, and is being investigated for use in the treatment of adenosine deaminase deficiency. Clare Thompson, *Umbilical Cords: Turning Garbage into Gold*, 268 SCIENCE 805, 805-06 (1995). Cord blood stem cell transplants have also been used to treat adrenoleukodystrophy, the disease of the young boy in the movie *Lorenzo's Oil*. Lilla Ross, *Our First Christmas: Present*, FLA. TIMES-UNION, Dec. 24, 1996, at A1.

5. FOOD AND DRUG ADMINISTRATION, PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS, [Dkt. No. 97N-0068], (Feb. 28, 1997) [hereinafter CELLULAR TISSUE FRAMEWORK].

dren. Nevertheless, the proposed cord blood regulation gave rise to great concern over whether it threatened the viability of the technology of cord blood stem cell collection and transplantation and infringed upon the rights of infants and their parents.⁶

Cord blood stem cell transplants were spotlighted in the media recently when the daughter of baseball hall-of-famer, Rod Carew, received a cord blood stem cell transplant⁷ as treatment for her fatal leukemia⁸ after attempts to find an appropriate bone marrow donor proved to be unsuccessful.⁹ Research regarding the use of allogeneic¹⁰ cord blood stem cells has been increasing. However, the majority of parents who are choosing to bank their babies' blood do so as biological insurance for their children rather than for general use, in hopes that they can provide their children with the gift of life should they ever need it.¹¹ The proposed cord blood regulations threatened to infringe upon a parent's right to make choices regarding their child's future. The proposed cord blood regulations also impact the child's property right to reclaim their stored cord blood for later use. In addition to foreclosing access to blood that has already been banked, the proposed cord blood regulation would have denied the child the right to bank its blood for later use. However, the proposed cord blood regulations were perceived as a necessary action in response to the advertising and banking of cord blood stem cells by various business entities.¹²

6. See generally, Comments submitted to the Food and Drug Administration, [Dkt. No. 96N-0002].

7. *A Rare Umbilical-Cord Infusion Gives Carew's Daughter Chance*, *NEWSDAY* Mar. 23, 1996, at 25.

8. Michelle Carew died from complications related to her leukemia within a month of the transplant. It is unknown whether the transplant came too late for Michelle, or whether cord blood transplants are ineffective in adults. Brian Alexander, *Life's Blood*, *SELF*, Aug. 1996, at 125, 127.

9. The likelihood of finding an unrelated donor is thirty to forty percent for Caucasians and decreases significantly for minorities, and the process of finding a donor may take anywhere from three to six months. In the event that an unrelated donor can be found, there is still a forty-five to ninety percent chance of the recipient developing graft-versus-host-disease. David T. Harris, *Experience in Autologous and Allogeneic Cord Blood Banking*, 5 J. HEMATOTHERAPY 123, 124 (1996).

10. "Allogeneic" refers to "molecules or cell types within a species that have identical functions but are antigenically distinct." *CONCEPTS IN IMMUNOLOGY AND IMMUNOTHERAPEUTICS* 503 (Jim Koeller, M.S. & Joseph A. Tami, Pharm. D. eds., 2d ed. 1992).

11. See Parents' Comments Submitted to the Food and Drug Administration, [Dkt. No. 96N-0002] (on file with the author).

12. Entities such as CorCell, Cord Blood Registry, ViaCord, and the New York Blood Center have been banking cord blood stem cells for parents of newborns consistent with industry standards set by the International Society for Hematotherapy & and Graft Engi-

This Comment examines the law leading up to the proposed cord blood regulations on umbilical/placental cord blood stem cells, and analyzes the impact of the proposed regulations on the infant, by examining the status of cord blood stem cells as a property interest. Next, this Comment considers whether the regulations would have acted as a deprivation of property without Due Process had they not been replaced by the Cell Tissue Framework. This Comment then reviews the Proposed Approach to Regulation of Cellular and Tissue-Based Products, and the appropriateness of the reconsideration of the Cord Blood Draft Document. Finally, this Comment concludes that the regulations would have deprived infants of the right to property without adequate Due Process, the regulations were more burdensome than necessary to effectuate the government interest, and that the Cellular Tissue Regulations are an appropriate framework under which cord blood stem cells should be regulated.

II. FDA DRAFT DOCUMENT CONCERNING THE REGULATION OF PLACENTAL/UMBILICAL CORD BLOOD STEM CELL PRODUCTS

The proposed cord blood regulations¹³ stated that the FDA had determined: (1) that it was appropriate to regulate placental/umbilical cord blood stem cell products as biologics as set forth in the Public Health Services Act;¹⁴ and (2) that cord blood stem cells fell within the definition of drugs and were subject to the regulations applicable to drugs¹⁵ within the Federal Food, Drug, and Cosmetic Act ("FDCA").¹⁶ The proposed regulations were very burdensome. First, the FDA's proposed cord blood regulations were far more restrictive than those required for blood products, even though blood product regulations would appear to have been the likely regulatory mechanism to use for cord blood stem cell products.¹⁷ Second, regulating cord blood stem cells as biologics renders them

neering ("ISHAGE"). FOUNDATION FOR THE ACCREDITATION OF HEMATOPOIETIC CELL THERAPY ("FAHCT"), STANDARDS FOR HEMATOPOIETIC PROGENITOR CELL COLLECTION, PROCESSING AND TRANSPLANTATION (May 1996).

13. See generally CORD BLOOD DRAFT DOCUMENT, *supra* note 1.

14. 42 U.S.C. §§ 262-263 (1994).

15. CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 4.

16. 21 U.S.C. §§ 310.100-310.546 (1996).

17. Additional Standards for Human Blood and Blood Products, 21 C.F.R. §§ 640.1-640.120 (1996). Blood collection and storage is subject to extensive regulation. The majority of regulations were imposed after the disaster in the 1980's in which blood untested for HIV had to be discarded. See 21 C.F.R. §§ 640.5(f), 610.45 (1996). Blood products are not, however, subject to an investigational new drug application ("IND") unless they have been extensively manipulated. FOOD AND DRUG ADMINISTRATION, DRAFT DOCUMENT

subject to FDA procedures for both establishment licensure¹⁸ and product licensure¹⁹ in order to ensure their safety, purity, and potency.²⁰ Third, cord blood stem cells that are intended for transplant into humans are further subject to the investigational new drug application ("IND")²¹ requirements during both the clinical development and licensure as final products.²² Finally, cord blood stem cells intended for use as source material for further manufacture were also to be subject to licensure, unless they could be covered previously under the licensure of the final product.²³

The proposed cord blood regulations indicated that cord blood stem cells were to be subject to an IND, a process normally utilized for the approval of drugs.²⁴ An IND must be submitted to the FDA when an investigator intends to conduct clinical investigations on an investigational new drug.²⁵ Although the IND mechanism has not been utilized in relation to transplants,²⁶ it has been required on clinical trials of gene therapy and trials of living autologous cells manipulated *ex vivo* that are intended for structural repair and reconstruction.²⁷ The IND process is

CONCERNING THE REGULATION OF PERIPHERAL BLOOD HEMATOPOIETIC STEM CELL PRODUCTS INTENDED FOR TRANSPLANTATION OR FURTHER MANUFACTURE INTO INJECTABLE PRODUCTS, (Feb. 1996). The FDA considers manipulated blood products to be biologics subject to establishment licensure, product licensure, and INDs. *Id.*

18. Establishment Licenses, 21 C.F.R. §§ 601.1-601.10 (1996). An establishment license is issued "only after inspection of the establishment and upon a determination that the establishment complies with the applicable standards prescribed in the regulations in this subchapter." 21 C.F.R. § 601.10(a).

19. Product Licenses, 21 C.F.R. §§ 601.20 (1996). The manufacturer must submit an application that includes "data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency." 21 C.F.R. § 601.2(a).

20. CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 3, 10.

21. The Code defines an "Investigational New Drug" as: "a new drug, antibiotic drug, or biological drug that is used in a clinical investigation." The term also includes a "biological product that is used *in vitro* for diagnostic purposes." Investigational New Drug Application, 21 C.F.R. § 312.3(b) (1996).

22. CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 5.

23. *Id.* at 10-11.

24. Investigational New Drug Application, 21 C.F.R. § 312 (1996).

25. *See supra* note 21 and accompanying text.

26. FDA has required several investigators to submit an IND in order to perform xenotransplants. In addition, the FDA has promulgated guidelines that require an IND for any investigator who intends to conduct xenotransplants. The FDA also intends to develop guidelines outlining the necessary requirements of an IND seeking approval of a xenotransplant request. DRAFT PUBLIC HEALTH SERVICE ("PHS") GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, 61 Fed. Reg. 49,920 (1996).

27. DEPARTMENT OF HEALTH AND HUMAN SERVICES, TRANSCRIPT OF PUBLIC HEAR-

properly used for biologics, which are considered, based upon their use, to be within the purview of drug regulations.²⁸ The IND process has not, however, been extended to blood products, particularly those which have not been manipulated.²⁹ It was thus inappropriate to extend the IND process to cover cord blood stem cell products.

The purpose of the FDA's proposed cord blood regulations was to ensure that blood cells do not contain transmissible agents, are not damaged, and that appropriate records are maintained.³⁰ None of the proposed cord blood regulations require, however, that the blood establishments show therapeutic effectiveness.³¹ The FDA has issued Draft Guidance in which it proposes to regulate peripheral blood stem cells, which are isolated from the circulating blood of the donor, with the same scheme utilized for blood products.³²

ING ON PRODUCTS COMPRISED OF LIVING AUTOLOGOUS CELLS MANIPULATED EX VIVO AND INTENDED FOR STRUCTURAL REPAIR AND RECONSTRUCTION (Nov. 16-17, 1995).

28. Essentially the IND regulations require that an investigator submit an application and then wait thirty days before performing any clinical studies. Investigational New Drug Application, 21 C.F.R. § 312 (1996). In addition to the application, the investigator must make assurances that he will refrain from performing clinical studies or restrict those studies at the request of the FDA. Investigational New Drug Application, 21 C.F.R. §§ 312.23(a), 312.40 (1996). Prior to participating in an investigation, the investigator must provide the sponsor with a completed Form FDA-1572, a curriculum vitae, and the clinical protocol. 21 C.F.R. § 312.53 (1996). Neither the sponsor nor the investigator is permitted to make a profit on an investigational drug until it has been granted final drug approval unless: "there is adequate enrollment in ongoing clinical investigations, (2) the price charged is limited to a 'cost recovery' level, (3) the drug is not commercially promoted or advertised, and (4) the sponsor of the drug is actively pursuing marketing approval." Kleinfeld et al., *Human Drug Regulations: Comprehensiveness Breeds Complexity*, in *FOOD AND DRUG LAW* 243, 282 (Richard M. Cooper ed., 1991).

29. See *FOOD AND DRUG ADMINISTRATION, DRAFT DOCUMENT CONCERNING THE REGULATION OF PERIPHERAL BLOOD HEMATOPOIETIC STEM CELL PRODUCTS INTENDED FOR TRANSPLANTATION OR FURTHER MANUFACTURE INTO INJECTABLE PRODUCTS* (Feb. 1996).

30. Joint Comments of Coriell Institutes For Medical Research and Corcell, Inc. submitted to the Food and Drug Administration, [Dkt. No. 96N-0002] (July 26, 1996) [hereinafter Joint Comments].

31. *Id.*

32. The Draft Document was distributed at Peripheral Blood Stem Cell Workshop, Transcript, Feb. 22-23, 1996; the workshop was announced in *PERIPHERAL BLOOD STEM CELLS: DISCUSSION OF PROCEDURES FOR COLLECTION, PROCESSING, AND PRODUCT CHARACTERIZATION; NOTICE OF PUBLIC WORKSHOP*, 61 Fed. Reg. 4786 (Feb. 8, 1996).

III. FOOD AND DRUG ADMINISTRATION: HISTORY LEADING UP TO THE REGULATIONS

The Public Health Service was created by an act of Congress³³ and is the independent agency from which the FDA derives its authority.³⁴ In 1927, the Federal Food and Drug Administration was created³⁵ to protect the public from unscrupulous manufacturers of medicines that were preying on the innocent in their quest for financial gain, and to give the FDA regulatory authority over foods, drugs, devices, and cosmetics.³⁶ Throughout the evolution of the agency, the FDA was eventually granted authority over foods,³⁷ drugs,³⁸ devices,³⁹ biological products,⁴⁰ and cosmetics.⁴¹

The Biologics Act⁴² was passed in 1902 in response to the deaths of more than ten school children following their vaccination with contaminated diphtheria antitoxin.⁴³ Initially, the Biologics Act was only intended

33. Public Health Services Act, 42 U.S.C. §§ 201-300 (1994).

34. Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 393 (1994).

35. *Id.*

36. See *Milestones in U.S. Food and Drug Law History* (visited Nov. 3, 1996), <<http://www.fed.gov/opacom/backgrounders/miles.html>>.

37. 21 U.S.C. §§ 312-350b (1994). Foods include "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(f) (1994).

38. 21 U.S.C. §§ 351-360b (1996). Drugs include:

(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1).

39. 21 U.S.C. §§ 351-353, 360 (1994). Devices include "instrument[s], apparatus, . . . and contrivance[s], including any component[s], part[s], or accessory, which is, — . . . (2) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals." Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h).

40. 42 U.S.C. §§ 262-263 (1994). Biological products include "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, or derivative, allergenic product, or analogous product or arsenphenamine or its derivative (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man." Public Health Service Act, 42 U.S.C. § 262(a) (1996).

41. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 361-363 (1994).

42. Biologics Act, 42 Public Health Service Act § 351, 42 U.S.C. § 262 (1996).

43. William R. Pendergast, *Biologic Drugs*, in *FOOD AND DRUG LAW* 306-308 (Richard M. Cooper ed. 1991).

to cover vaccines.⁴⁴ Congress specifically amended the Act in 1970 to include blood and blood components or derivatives.⁴⁵ Following the transfer to the FDA of the authority to enforce the Biologics Act in 1972, the FDA applied several provisions of the FDCA to blood products.⁴⁶

The impetus for the FDA's decision to regulate cord blood stem cells was the numerous inquiries from physicians and parents, resulting from assertions made by the industry while soliciting parents to bank their babies' cord blood.⁴⁷ Companies were promising parents the world, the stars, and the hope that they could provide the one thing that one day might save their baby's life — a transplant. The cord blood banking service was offered to parents with family histories of blood diseases and cancers, those with a child suffering from a life threatening illness, as well as those whose children had very little risk of ever falling victim to a life threatening disease treatable with a cord blood transplant.⁴⁸ In addition, there was a great deal of concern within the industry that premature commercialization could stunt the potential growth of the technology before it had an opportunity to generate adequate research on the safety and efficacy of the procedure.⁴⁹ In sum, the FDA was particularly concerned with what it referred to as the "vigorous commercial activity" in cord blood stem cell banking.⁵⁰

IV. BACKGROUND OF UMBILICAL CORD BLOOD STEM CELL TRANSPLANTS

A. *Scientific Theory Behind the Procedure*

1. *Possible Superiority Over Bone Marrow Transplants*

Umbilical cord blood stem cells⁵¹ have always been disposed of with

44. *Id.*

45. Public Health Service Act, 42 U.S.C. § 300ff-72 (1996). *See also* Current Good Manufacturing Practices for Blood and Blood Components, 21 C.F.R. § 606 (1996); Establishment Registration and Product Licensing for Manufacturers of Human Blood and Blood Products, 21 C.F.R. § 607 (1996). *See also* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 678 (2d ed. 1991).

46. *See id.* at 681.

47. Susan Cohen, *Whose Blood Is It Anyway?*, WASH. POST MAG., Aug. 18, 1996, at 11, 15.

48. *See* Cord Blood Registry (visited Oct. 27, 1996) <<http://www.cordblood.com>>.

49. Cohen, *supra* note 47, at 27.

50. *Id.* at 29.

51. Hal E. Broxmeyer et al., *Human Umbilical Cord Blood as a Potential Source of Transplantable Hematopoietic Stem/Progenitor Cells*, 86 PROC. NAT'L. ACAD. SCI. U.S.A. 3828 (1989).

the rest of the waste material after birth. However, due to advances in medicine the life-giving potential of the cord blood has recently been discovered. The umbilical cord blood is rich with pluripotent⁵² stem cells that are capable of proliferating into the various blood components that comprise whole blood.⁵³ It is the proliferative potential of the pluripotent stem cells that make them viable substitutes for a traditional bone marrow transplant.⁵⁴ Cord blood stem cells possess other advantages over the typical bone marrow transplant.⁵⁵ They can be harvested after birth, thereby avoiding the invasive procedure harvesting bone marrow from a donor requires.⁵⁶ Additionally, the likelihood that the cord blood stem cells will carry infectious agents⁵⁷ is lower than bone marrow from an adult donor since the source is a new infant who is less likely to have been exposed to various sensitizers or allergens.⁵⁸ Finally, the immature state of the stem cells indicates that the recipient is less likely to be sensitive to slight HLA⁵⁹ mismatches, and as a result, use of the stem cells may decrease the risk of graft-versus-host disease.⁶⁰

52. Each pluripotent stem cell is capable of not only dividing into two identical cells, but it may also develop into the different types of cells that make up blood until all the necessary components are represented. Elise Hancock, *Stalking the Stem Cell*, *JOHNS HOPKINS MAG.*, June 1996, at 37, 39.

53. Whole blood is comprised of erythrocytes, granulocytes, monocytes, megakaryocytes, platelets, T-lymphocytes, B-lymphocytes, and plasma. ARTHUR C. GUYTEN, M.D., *TEXTBOOK OF MEDICAL PHYSIOLOGY* 357 (8th ed. 1991).

54. Bone marrow also contains cells capable of proliferating into whole blood, however, the stem cells in bone marrow are much more mature than those in the umbilical cord and require a closer match than that which is necessary for cord blood. Richard Saltus, *Umbilical Cord Cells Eyed for Transplants*, *BOSTON GLOBE*, July 18, 1996, at A3.

55. *Stem Cell Transplants Soon May Render Marrow Transplants Obsolete*, *F-D-C REPORTS* ("THE PINK SHEET"), Mar. 13, 1995.

56. Bone marrow donors must undergo anesthesia and painful surgery in order to harvest their marrow. *Blood From Placenta Can Aid Leukemia Patients*, *N.Y. TIMES*, July 18, 1996, at A19.

57. Cord blood transplants are rarely infected with viruses such as cytomegalovirus (CMV) or Epstein-Barr virus ("EBV") which may cause problems for a transplant recipient. Cord Blood Transplants (visited Oct. 29, 1996) <<http://cancer.med.upenn.edu/specialty/chemo/bmt/newsletter/N33/cord.html>>.

58. A sensitizer is "a substance that causes dermatitis only after alteration (sensitization) of the skin by previous exposure to that substance." *STEDMAN'S MEDICAL DICTIONARY* 1597 (26th ed. 1995).

59. HLA antigens are located on the surfaces of all cells. There are nearly 150 different antigens which are coded for by only 6 genes. It is nearly impossible for two people to have the exact same six HLA antigens and any variation may be responsible for rejection. GUYTEN, *supra* note 53, at 389.

60. Joan Stephenson, Ph.D., *Terms of Engraftment: Umbilical Cord Blood Transplants Arouse Enthusiasm*, 273 *JAMA* 1813, 1814 (1995).

The benefits of cord blood transplants⁶¹ over traditional bone marrow transplants⁶² seem overwhelming. However, there are limitations to the effectiveness of the procedure. Whether cord blood transplants will be successful in adults is debatable. Specifically, one may question whether the cord blood contains sufficient stem cells to repopulate an adult body adequately.⁶³ The majority of recipients thus far have been under 70 kilograms (156 pounds) and have shown promising success.⁶⁴ There also have been reports of successful cord blood transplants in patients weighing up to 81 kilograms (178 pounds), contradicting the apparent correlation between the effectiveness of the transplant and the patient's weight.⁶⁵

Graft-versus-host disease⁶⁶ is a life-threatening complication possible in all transplants, but the lower incidence in a cord blood transplant may not necessarily be as favorable as one might believe. For example, leukemia patients appear to benefit from a slight graft-versus-leukemia effect,⁶⁷ which helps to eradicate the patient's system of any remaining cancerous cells.⁶⁸ To eliminate this effect entirely may prove detrimental to the overall therapy.⁶⁹

61. The procedure for both cord blood stem cell transplants and bone marrow transplants are largely the same. Essentially, the patient has her bone marrow and cancerous cells eliminated using chemotherapy or radiation and then the stem cells or bone marrow progenitor cells are infused into the patient to give rise to the patient's blood production system and immune system. Stephenson, *supra* note 60, at 1814.

62. Bone marrow transplant procedures involve irradiating the patient's existing bone marrow and then infusing the patient with the donated marrow. Following the initial procedure the patient must undergo extensive anti-rejection therapy which suppresses the immune system. Although the ultimate transplants procedures are very similar, the bone marrow transplant requires a harvest from a matched donor. Assuming that a suitable donor has been located, the bone marrow recovery process is a painful, invasive procedure that often involves general anesthesia. *The International Cord Blood Foundation* (visited Oct. 29, 1996) <<http://www.infinityweb.com/cordblood/faq.html>>.

63. Jean-Philippe Laporte et al., *Cord-Blood Transplantation From and Unrelated Donor in an Adult with Chronic Myelogenous Leukemia*, 335 NEW ENG. J. MED. 167 (1996).

64. *Cord Blood Transplants*, *supra* note 57

65. *The International Cord Blood Foundation ("ICBF")* (visited Oct. 29, 1996) <<http://www.com/cordblood/brochure.html>>.

66. Graft-versus-host-disease is "a pathological reaction that is caused by the transplantation of competent T cell into an incompetent host, that is, one unable to reject them. This reaction occurs when the donor cells attack the host." CONCEPTS IN IMMUNOLOGY AND IMMUNOTHERAPEUTICS, *supra* note 10, at 509.

67. Graft-versus-leukemia effect is "the decreased incidence of leukemia relapses seen in patients receiving allogeneic transplants in comparison with autologous transplants." *Id.*

68. See Cohen, *supra* note 47, at 15.

69. See *id.*

2. *The Difference Between Allogeneic and Autologous Transplants*

The distinction between autologous⁷⁰ and allogeneic⁷¹ transplants is that autologous transplants are banked for use by the donor, and the donor does not intend to permit the sample to be used in the general population but rather only for himself. The difficulties of finding an appropriate donor match are not present in autologous transplants because of the elimination of the risks of graft-versus-host disease and rejection.⁷² Allogeneic samples are banked for use by the general population. Therefore, the donor and the recipient are generally unknown to one another; much like the banking of whole blood.⁷³ Alternatively, the donor may designate the person to receive the allogeneic transplant. It is possible to bank a sample for either autologous or allogeneic transplant, and it is up to the donor — actually, the newborn donor's parents — to designate the purpose for which the sample will be used.

3. *Preservation Procedures*⁷⁴

The preservation of cord blood is a simple, painless, and minimally invasive procedure. The collection center selected by the expectant mother to bank her baby's cord blood sends her a collection kit. She must bring the collection kit with her to the delivery room.⁷⁵ The physician is shown a short five-minute instructional video on the retrieval process that is very similar to a standard phlebotomy.⁷⁶ The umbilical cord is clamped after delivery of the baby, and blood is withdrawn into syringes either while the placenta is still *in utero* or after it has been delivered.⁷⁷ At this time,

70. "Autologous" refers to a transplants where the donor and the recipient are the same individual, for instance, skin grafts. *STEDMAN'S MEDICAL DICTIONARY*, *supra* note 58, at 170.

71. "Allogeneic" refers to a transplant within a species. *STEDMAN'S MEDICAL DICTIONARY*, *supra* note 58, at 34.

72. Alexander, *supra* note 8, at 125-26.

73. Cohen, *supra* note 47, at 26. The New York Blood Center has been banking cord blood stem cells for autologous use as a participant in a National Heart, Lung and Blood Institute pilot study. *Id.*

74. See generally Robert A. Dracker, *Cord Blood Stem Cell: How to Get Them and What to Do with Them*, 5 J. HEMATOTHERAPY 145 (1996).

75. *Cord Blood Collection Information*, *supra* note 2. The Cord Blood Registry kit contains: three 60 cc pre-heparinized syringes, three 18 gauge needles, two plastic bags, and insulated packaging for shipping with labels. *Id.*

76. COLLECTION PROCEDURES FOR UMBILICAL CORD BLOOD STEM CELL SAMPLES (Cord Blood Registry 1995); *Umbilical Cord Blood for Bone Marrow Transplantation*, 38 MED. LETTER 2 (Aug. 16, 1996).

77. Caesarean deliveries will also produce bankable cord blood samples. *Cord Blood Collection Information*, *supra* note 2.

aliquots are taken for testing, HLA-typing, cell counts, and other future testing.⁷⁸ An anticoagulant and a cryopreservative are added to the cord blood sample, and then the cord blood is stored under liquid nitrogen.⁷⁹ The cord blood must then be received by the collection center⁸⁰ within twenty-two hours.⁸¹ An average collection is 75 to 80 cubic centimeters ("cc"), but any volume between 40 cc to 200 cc will be sufficient for banking.⁸²

4. Potential Treatment for Many Life-threatening Diseases

Cord blood transplants present many possibilities for treating life-threatening diseases.⁸³ The nature of blood in the human circulatory system makes therapies involving blood a promising treatment for blood diseases. The first cord blood transplants⁸⁴ were conducted while researching treatments for Fanconi's anemia.⁸⁵ Today efforts have been

78. *Umbilical Cord Blood for Bone Marrow Transplantation*, *supra* note 76, at 2.

79. There is some disagreement as to the viability of tissues stored in deep freeze and the length of time that those tissues will remain viable. A bank in Vancouver, British Columbia indicates that cord blood may be held and remains transplantable for up to fifteen years, however, since the cells are held in suspended animation, in theory, they may be preserved indefinitely. *Lifebank Cryogenics* (visited Oct. 29, 1996) <<http://www.lifebank.com/faq.html>>.

80. The samples are mailed by overnight courier which creates the interstate nexus required for FDA regulation.

81. The outside window for final processing is 48 hours, but a larger sample has been processed up to 72 hours after collection. *Cord Blood Collection Information*, *supra* note 2.

82. *Id.*

83. See generally CORD BLOOD REGISTRY, UMBILICAL CORD BLOOD BANKING: A NEW BIRTH OPTION FOR YOUR FAMILY 2 (1997); David Brown, *Umbilical Cord Blood Found Useful In Fighting Disease*, WASH. POST, July 13, 1996, at A3; Lucette Lagnado, *Cell Transplants From Newborns Found Major Help in Fighting Blood Cancers*, WALL ST. J., July 18, 1996, at B5.

84. The first successful transplant was performed in France in 1988 on a five year old child with Fanconi's's Anemia. The patient's newborn sister was a perfect match, but was too young to donate bone marrow. Given the gravity of the illness, researchers transplanted cord blood stem cells preserved from the sister's umbilical cord and placenta, and thereby the patient's bone marrow was restored. Eliane Gluckman, M.D. et al., *Hematopoietic Reconstitution in a Patient with Fanconi's's Anemia by Means of Umbilical-Cord Blood From an HLA-Identical Sibling*, 321 NEW ENG. J. MED. 1174 (1989). See also *Cord Blood Stem Cell Transplants* (visited Oct. 29, 1996) <<http://www.fhcr.org/~pubrel/CNes1996/Jan4/Cord.htm>>; *Cord Blood Transplants*, *supra* note 57.

85. Fanconi anemia is an inherited anemia that leads to aplastic anemia and bone marrow failure. The disease often presents itself between the ages of 3 and 12 with extreme fatigue and continual colds and viral infections. A recent study indicates that Fanconi anemia patients develop leukemia or other cancers. *Fanconi Anemia Fact Sheet* (visited Oct. 28, 1996) <http://www2.cybernex.net/~jj/fa_facts.html>.

made to utilize the advances in genetic research, coupled with cord blood research, to treat such illnesses as adenine deaminase deficiency,⁸⁶ thalassemia,⁸⁷ sickle cell anemia,⁸⁸ and other genetically linked disorders.⁸⁹ Researchers hope the genetic technology used to treat genetically linked diseases may one day be effective in the treatment of AIDS.⁹⁰

B. Future of Research for Cord Blood Stem Cell Transplants

The research into cord blood transplants is forging ahead with each success. Cord blood holds so much potential that the National Heart Lung and Blood Institute ("NHLBI") has proposed funding,⁹¹ out of its own budget, for a study into cord blood banking.⁹² The study is projected to proceed for five years,⁹³ and will support two to four unrelated donor banks, six to eight transplant centers, and one coordinating center.⁹⁴ The NHLBI hopes the study will establish the viability of cord blood transplants as well as appropriate preservation procedures.⁹⁵

The proposed cord blood regulations would have had a major impact on the progress of the research by requiring the submission of an IND application, a process which would itself restrict access to cord blood stem cells that have been banked.⁹⁶ Moreover, the requirements would have acted as a roadblock to patients desperately needing the life-saving therapy. The costs associated with the IND and the subsequent new drug

86. Adenine deaminase deficiency is a fatal genetic deficiency that is treated by inserting normal genes into the cord blood then transplanting them into the infant. Cohen, *supra* note 47, at 29.

87. Surapol Issaragrisil, *Cord Blood Transplantation in Thalassemia*, 20 BLOOD CELLS 259 (1994). See also Gluckman, et al., *supra* note 84, at 1174.

88. "Sickle cell anemia" is a "chronic familial anemia in which a large proportion or majority of the red cells in the blood are sickle cells and which occurs mainly in persons of Negro blood." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2111 (1986).

89. Stephenson, *supra* note 60, at 1813.

90. Researchers plan to insert an HIV-resistant gene into cord blood collected from a baby born to an HIV infected mother. The baby will still be HIV positive, but will not develop the signs and symptoms of AIDS. Angela Gonzales, *Unbillical Blood Could Fight HIV*, BUS. J. - PHEONIX & VALLEY SUN, Mar. 19, 1995, at 29.

91. The amount allocated to the five-year study is 25 million dollars. Alexander, *supra* note 8, at 159.

92. Cohen, *supra* note 47, at 29.

93. NHLBI Will Submit Stem Cell IND to FDA For Five Year Project to Study Cord Blood Bank Viability, F-D-C REPORTS ("THE BLUE SHEET"), Dec. 20, 1995, at 5-6.

94. National Heart Lung and Blood Institute, Request for Proposals (July 1996).

95. NHLBI Will Submit Stem Cell IND to FDA For Five Year Project to Study Cord Blood Bank Viability, *supra* note 93, at 5-6.

96. See generally Comments submitted to the Food and Drug Administration, [Dkt. No. 96N-0002].

application ("NDA")⁹⁷ would have caused cord blood stem cell banking fees to skyrocket above their already high levels because cord blood banks would be required to conduct studies and submit the requisite data.⁹⁸ Because investigational status would have been conferred upon cord blood transplants patients would have limited access to the procedure because health insurance companies would have used the investigational status to justify denying insurance benefits and most patients would be unable to finance their own transplant.⁹⁹ Patients would have had access to the procedure within the proposed cord blood regulations, but only through compliance with the rigorous requirements.

C. Public Response to the FDA Proposed Cord Blood Regulations

The FDA received an overwhelming response to the publication of the proposed cord blood regulations in the form of comments submitted to the docket.¹⁰⁰ The majority of the comments were submitted by concerned parents and medical personnel expressing alarm and apprehension about the FDA's proposed mechanism to regulate cord blood stem cell transplants in a manner similar to drugs through the IND process.¹⁰¹ The majority of the parents understood that the regulatory mechanism parallels that of drugs; it meant that cord blood stem cell transplants were doomed to suffer the same delays afflicting new drugs.¹⁰² A seven to fourteen year wait, typical for new drug approval, is unacceptable to parents whose children are dying of blood related diseases that could be treated and potentially cured today through a cord blood transplant. Furthermore, those parents who had already banked their baby's blood were concerned that the FDA would deny them access to the blood when they really needed it.¹⁰³ That concern raises a constitutional question of parents' rights to bank their babies' tissue, and ultimately, the rights to access it at will. Additionally, the industry objected to the method by which

97. 21 C.F.R. pt. 314 (1997).

98. See Comments of Cord Blood Registry, submitted to the Food and Drug Administration, [Dkt. No. 96N-0002] (Jul. 26, 1996) [hereinafter Cord Blood Registry Comments].

99. See *id.*

100. FDA has received over 500 comments submitted to Docket No. 96N-0002. See generally Comments submitted to the Food and Drug Administration, [Dkt. No. 96N-0002].

101. See Cord Blood Registry Comments, *supra* note 98, at Attachment 1.

102. See generally Comments submitted to the Food and Drug Administration, [Dkt. No. 96N-0002].

103. See generally *id.*

the proposed cord blood regulations were promulgated.¹⁰⁴ The proposed cord blood regulations were promulgated without utilizing notice-and-comment procedures required by the Administrative Procedure Act.¹⁰⁵ Moreover, the proposed cord blood regulations simply presumed interim compliance with the regulations.¹⁰⁶

V. PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS

The FDA held a series of meetings to elucidate the technical issues related to cord blood stem cell collection, preparation, processing, storage, and characterization.¹⁰⁷ At the conclusion of these meetings, the FDA acknowledged that the traditional regulatory scheme used for other biologicals may not be appropriate for peripheral and cord blood hematopoietic stem/progenitor cells and other cellular and tissue-based products. Thus, the proposed cord blood regulations were inappropriate. The FDA then released the Proposed Approach to Regulation of Cellular and Tissue-Based Products ("Cellular Tissue Framework").¹⁰⁸

The Cellular Tissue Framework creates a tiered approach to regulating human cellular and tissue-based products — including cord blood stem cells. The framework focuses on preventing the use of contaminated tissues that carry the potential to transmit infectious diseases,¹⁰⁹ preventing mishandling or improper processing that might result in contamination or products that are of inadequate quality,¹¹⁰ and ensuring that clinical safety and efficacy are demonstrated for highly processed tissues, tissues used for non-homologous uses, tissues combined with non-tissue components, or have a systemic effect.¹¹¹ It was the FDA's intention to provide the minimum federal regulatory requirements and increase the requirements commensurate with the potential risks.

104. See Cord Blood Registry Comments, *supra* note 98, and Joint Comments, *supra* note 30.

105. Administrative Procedure Act, 5 U.S.C. § 553(b) (1996). See also Cord Blood Registry Citizen's Petition for Stay of Administrative Action (June 6, 1996) [hereinafter Citizen's Petition](on file with the author).

106. CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 1.

107. PUBLIC WORKSHOP, PROCEDURES FOR PREPARATION AND STORAGE OF CORD BLOOD STEM/PROGENITOR CELLS FOR TRANSPLANTATION, 60 Fed. Reg. 58,088 (Nov. 24, 1995); PUBLIC WORKSHOP, PROCEDURES FOR THE PREPARATION OF HUMAN PERIPHERAL BLOOD STEM/PROGENITOR CELLS, 61 Fed. Reg. 4,786 (Feb. 8, 1996).

108. CELLULAR TISSUE FRAMEWORK, *supra* note 5.

109. *Id.* at 6, 8.

110. *Id.* at 11.

111. *Id.* at 20.

The FDA intends to phase in the requirements, beginning with registration and listing, utilizing an electronic system in development by the FDA. The Agency also intends to require communicable disease testing, and to develop and promulgate processing standards. Following the development of processing standards, the FDA then plans to issue licenses based on the certification that is submitted with the registration and listing.¹¹²

The Cellular Tissue Framework is a rational response to the valid concerns of the industry and concerned citizens. A tiered approach, whereby autologous stem cells are subject to minimal regulations and allogeneic stem cells for non-family members are subject to greater regulatory control addresses the concerns of the FDA without ignoring the needs of individuals.

A. Autologous Stem Cells and Allogeneic Stem Cells For Use In Family Members

Submission of clinical safety and effectiveness data for cord blood stem cells for allogeneic or related family use, provided the cells are minimally manipulated and not combined with other non-tissue components is not required.¹¹³ Screening and testing of the donor and the banked stem cells are to be conducted prior to banking and release.¹¹⁴ The FDA has determined that cells to be used from a family-related donor must be tested, but that the family shall make the ultimate decision whether to utilize contaminated cells. Cells to be banked and used later by the donor are subject to less stringent requirements. The framework recommends that cells to be used by family members undergo the same testing, however, it does not make such testing a requirement.¹¹⁵ Specifically, because cord blood stem cells are rich in leukocytes they should be tested for human T-cell lymphotropic virus ("HTLV"), and cytomegalovirus ("CMV"). Other testing should include HIV, HCV, HBV, and screening for those who are high risk for HIV and Hepatitis. While there will be no premarket requirements concerning communicable disease testing in allogeneic circumstances, the FDA retains authority to inspect banking facilities.

112. *Id.* at 26-27.

113. CELLULAR TISSUE FRAMEWORK, *supra* note 5, at 20-21.

114. *Id.* at 13.

115. *Id.* "[S]creening and testing procedures would be recommended rather than required for such autologous [use] . . . because 1) autologous use of cells . . . raises lesser communicable-disease concerns than does allogeneic use. . . ." *Id.*

The Cellular Tissue Framework considers cord blood stem cells to be a homologous use and in some instances, possessing a metabolic function.¹¹⁶ When cord blood stem cells are used for allogeneic use in a family member, the Cellular Tissue Framework imposes premarket requirements until sufficient clinical safety and effectiveness obviate the need for data prior to marketing.¹¹⁷ Cord Blood Stem Cells are subject to handling and processing requirements including registration, listing, and reporting. Additionally, the FDA intends to promulgate Good Tissue Practice requirements aimed at preventing contamination and preserving product integrity.¹¹⁸

B. Allogeneic Stem Cells For Non-Family Use

Minimally manipulated stem cells for unrelated allogeneic use are regulated as biologic drugs under the FDCA. Currently, the Cellular Tissue Framework requires banks to follow donor screening, product testing, and quarantine procedures for stem cells to be used for allogeneic use — including familial use. Allogeneic cells must undergo testing for HIV, CMV, HTLV, syphilis, treponemapallidum, and hepatic infection. Any cells testing positive must be labeled “BIOHAZARD,” but may be used in limited circumstances, such as rare histocompatibility matches. If this case arises, use may be obtained with a written informed consent and concurrence in writing by the recipient’s physician.¹¹⁹

Cord blood stem cells banked for allogeneic use in non-family members are subject to processing controls such as product chemistry, manufacturing, and controls (“CMCs”) and premarket submissions. The Agency will phase-in the IND and licensure submissions and intends to eliminate the IND as soon as it is able to make a finding of safety and effectiveness.¹²⁰ During the interim period, the FDA does not intend to require licensure, although establishment registration and product listing will be mandatory.

116. *Id.* at 18.

117. *Id.* at 21.

118. *Id.*

119. *Id.* at 26.

120. *Id.* at 22; see REQUEST FOR PROPOSED STANDARDS FOR UNRELATED ALLOGENEIC PERIPHERAL AND PLACENTAL/UMBILICAL CORD BLOOD HEMATOPOIETIC STEM/PROGENITOR CELL PRODUCTS; REQUEST FOR COMMENTS, 63 Fed. Reg. 2985, Jan. 20, 1998.

VI. CONSTITUTIONAL RAMIFICATIONS OF THE PROPOSED CORD BLOOD REGULATIONS

While the ramifications of the proposed cord blood regulations were cause for concern, the impact of the FDA's regulatory scheme on individual constitutional rights was particularly troubling.¹²¹ The Fifth Amendment guarantees the right to property as an inherent right of all citizens.¹²² It is a basic principle of law that the government may not deprive a citizen of property without due process. Should the government need to deprive an individual of property it may do so no more than is necessary to further a legitimate government interest.¹²³ Assuming arguendo, that cord blood is indeed property, the FDA must provide individual citizens with due process, and the government interest must be great, before the government may cause a person to relinquish the most intrinsic property interest — life.

Parents making the decisions to store their infants' cord blood are asking banks to act as custodians of their babies' cord blood.¹²⁴ The parents are not, however, transferring the title to their babies' cord blood; thus, it is questionable whether cord blood banks have the right to file for an IND on products that they do not own outright.¹²⁵ The FDA's proposed cord blood regulations would have effectively denied a person access to that which is, arguably, the individual's own property. Furthermore, the government would have lacked a sufficiently compelling¹²⁶ reason to do so, therefore, constituting a violation of the Fifth Amendment in that the intrusion would limit a procedure that is not intended to have an effect on the public, but rather the individual responsible for banking the blood in the first place. There are two issues to be resolved when analyzing the procedural protection of property within the Fifth Amendment: whether

121. U.S. CONST. amend. V.

122. *Id.*

123. 16A AM. JUR. *Constitutional Law* § 845 (1979).

124. *See* Cord Blood Registry Comments, *supra* note 98.

125. The relationship is essentially that of a bailment where there is a, delivery of goods or personal property, by one person (bailor) to another (bailee), in trust for the execution of a special object upon or in relation to such goods, beneficial either to the bailor or bailee or both, and upon a contract, express or implied, to perform the trust and carry out such object, and thereupon either to redeliver the goods to the bailor or otherwise dispose of the same in conformity with the purpose of the trust.

BLACK'S LAW DICTIONARY 141-42 (6th ed. 1990).

126. *Roe v. Wade*, 410 U.S. 113, 163 (1973) (the Supreme Court held that protecting a viable fetus in the third trimester was a compelling justification for state intrusion of personal autonomy).

an item is property and whether the government's action deprives a person of that property.¹²⁷

A. *Organs are Personal Property*

The Fifth Amendment guarantees that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law,"¹²⁸ but the extent of the protection may vary. The traditional bundle of rights associated with property are possession, exclusion,¹²⁹ use and disposition, enjoyment of the fruits or profits, and destruction.¹³⁰ In the United States, the government cannot deny a person the right to the organs contained within his or her body. The law is not clear, however, as to whether the government can deny a person the right to organs which are outside that person's body.

Traditionally, interests related to a person have been defined as liberty interests, and thus, enjoy Constitutional protection.¹³¹ Items such as cord blood stem cells, on the other hand, which have been removed from the person would be divested of the personal element that denotes a liberty interest. This would place them squarely within the definition of an item subject to a property interest for which there are recognized constitutional protections.¹³²

It seems elementary that a person's organs are that person's property¹³³ in which she has a property interest; unfortunately, however, the

127. JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW 513 (4th ed. 1991).

128. U.S. CONST. amend. V.

129. *Arnaud v. Odom*, 870 F.2d 304, 304 (5th Cir. 1989) (the court stated that "property implies a right to exclude; you have a right to exclude from your body; therefore your body is property").

130. Eric S. Jaffee, "*She's Got Bette Davis[s] Eyes*": *Assessing the Nonconsensual Removal of Cadaver Organs Under the Takings and Due Process Clauses*, 90 COLUM. L. REV. 528, 548-49 (1990).

131. See NOWAK & ROTUNDA, *supra* note 127, at § 13.4.

132. See BLACK'S LAW DICTIONARY, *supra* note 125, at 1217 (defining personal property as "everything that is the subject of ownership . . . or any right or interest which one has in things moveable. Generally, . . . goods, chattels, money, notes, bonds, stocks, and choses in action generally, including intangible property"). See also 63 AM. JUR. 2D *Property* § 1 (1997) (stating that "as a matter of legal definition, 'property' refers not to a particular material object but to the right and interest in an object. 'Property' in a thing does not consist merely in its ownership or possession, but also in the lawful unrestricted right of its use, enjoyment, and disposal.")

133. It is important to draw the distinction between property interests and liberty interests. Property interests exist in objects or things while liberty interests exist in persons. Jaffee, *supra* note 130, at 553.

law is not that clear. The United States Supreme Court has stated that the traditional determination of property is based on an entitlement¹³⁴ rather than expectancies.¹³⁵ The National Organ Transplant Act ("NOTA")¹³⁶ does not permit a person to sell his or her organs, yet the sale of bodily fluids such as plasma and sperm is permitted.¹³⁷ The ability to sell the latter items imply that they are property in which a person has a valid property interest. The Uniform Anatomical Gift Act ("UAGA")¹³⁸ permits a person to donate all or any portion of one's body upon death.¹³⁹ Although the UAGA permits a person to donate her organs upon death, she may not arrange to sell her organs per NOTA's prohibition.¹⁴⁰

A person has the undeniable right to use her body as she see fit, but it is not an absolute right.¹⁴¹ That right is subject to certain statutory and public policy supported limitations.¹⁴² Technology has only recently advanced to the point where the courts have needed to address whether a person truly has a property interest in her organs and tissues.¹⁴³ Histori-

134. *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). The Court stated that property interests are not created by the Constitution, but that they are created and defined by rules and understandings stemming from an independent source that secures certain benefits and support claims of entitlement. *Id.*

135. *Id.*

136. National Organ Transplant Act, Title III, § 301, (codified at 42 U.S.C. § 274e (Supp. V 1987)).

137. Fred H. Cate, *Human Organ Transplantation: The Role of Law*, 20 J. CORP. L. 69, 76-77 (1995).

138. Unif. Anatomical Gift Act § 2(a), (e)(1968) (adopted in some form in every state). See also Cate, *supra* note 137, at 76-77.

139. Unif. Anatomical Gift Act ("UAGA") § 3 (1968). The following people may be donees of anatomical gifts:

- (1) any hospital, surgeon, or physician, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or
- (2) any accredited medical or dental school, college or university for education, research, advancement of medical or dental science, therapy; or
- (3) any bank or storage facility, for medical or dental education, research, advancement of medical or dental science, therapy, or transplantation; or
- (4) any specified individual for therapy or transplantation needed by him.

Unif. Anatomical Gift Act § 3.

140. National Organ Transplant Act, (codified as amended at 42 U.S.C. §§ 273-274e (1988)).

141. It appears that state laws regarding prostitution and sodomy are limitations on the rights of an individual to utilize their body as they see fit. Additionally, the conflict regarding abortions, forced sterilization, and vaccination laws are areas of contention with regard to whether a person can treat his body as he wishes. See Jaffee, *supra* note 130, at 544.

142. *Id.*

143. See William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693 (1995).

cally, society's recognition of bodily property rights has spanned the spectrum—from a wife as chattel to the enslavement of African-Americans.¹⁴⁴ The common law¹⁴⁵ and the UAGA further recognized a quasi-property right in a cadaver that vests in the decedent's nearest relative.¹⁴⁶ In addition, a property interest in a person's body is also recognized in the common law torts of assault and battery.¹⁴⁷ Finally, one court has stated that "[a] person of adult years and in sound mind has the right, in the exercise of control over his body, to determine whether or not to submit to lawful medical treatment."¹⁴⁸

Recently, the issue of whether a person's tissues and cells constitute a property interest has arisen in the context of claims of conversion.¹⁴⁹ In *Moore v. Regents of the University of California*,¹⁵⁰ the California Supreme Court held that the plaintiff did not have a claim for conversion when his physician took excised cells from the plaintiff's body and ultimately patented the cell line.¹⁵¹ The court held that the patient did not expect to retain control over his cells following their removal, and thus found that he was not entitled to any property interest in the cells.¹⁵² The court did not decide the issue of whether a person could have a property interest in his tissues, specifically those which have been removed from the body. The court noted that Moore did not have a property interest in cells over which he had no intention of retaining control.¹⁵³ Nevertheless, the court found that Moore did have a cause of action against the physician for breaching his fiduciary duty and for failing to obtain informed consent, which together, were sufficient to provide redress for

144. *Id.*

145. See Jaffee, *supra* note 130, at 543 n.66 (citing *In re Johnson*, 612 P.2d 1302, 1305 (N.M. 1980)).

146. The UAGA designates those who may donate the deceased organs, thereby implying that the specified person has at least a limited property interest in the deceased's body. Unif. Anatomical Gift Act. § 2 (1968).

147. A person has a right to have his person be free from assaults and batteries. See generally 6A C.J.S. *Assault & Battery* §§ 4-12 (1975).

148. *Cobbs v. Grant*, 502 P.2d 1 (Cal. 1972).

149. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

150. *Id.*

151. *Id.* at 481-82. Moore was undergoing medical treatment at the Medical Center of the University of California at Los Angeles for hairy-cell leukemia. As a result, Moore underwent a splenectomy upon the advice of his physician. After the removal, Moore's physician took portions of his spleen for use in research in order to initiate a cell line. The cells line was developed and ultimately patented. Based on Moore's allegations, he asserted 13 causes of action each of which was demurred by the plaintiffs. *Id.*

152. *Id.* at 489.

153. *Id.*

Moore's injuries.¹⁵⁴ The court's holding, however, left open the possibility of a future recognition of a property interest in a person's cells where that person intends to retain control over those cells upon removal from his body. This is precisely where parents have chosen to bank their infants' cord blood.

In a case following *Moore*, the California Supreme Court held that a decedent's cryogenically preserved sperm was his "property" over which a probate court had jurisdiction to determine disposition.¹⁵⁵ The issue in *Hecht v. Kane*¹⁵⁶ arose when the decedent's live-in girlfriend, Deborah Hecht, attempted to reclaim his sperm from the custodial care of the sperm bank in which it had been deposited.¹⁵⁷ Just before he took his own life, the decedent assiduously made deposits in a sperm bank for later use by Hecht.¹⁵⁸

In both his will and suicide letter to his children, the decedent indicated his desire that Hecht should become impregnated with his sperm and bear his child posthumously.¹⁵⁹ The court held that the decedent had a property interest, which could appropriately be willed to Hecht.¹⁶⁰ The court explained its divergence from the general law of personal property by recognizing in gametic material "an interim category that entitles

154. The court stated:

We need not, however, make an arbitrary choice between liability and nonliability. Instead, an examination of the relevant policy considerations suggests an appropriate balance: Liability based upon existing disclosure obligations, rather than an unprecedented extension of the conversion theory, protects patients' rights of privacy and autonomy without necessarily hindering research.

Id. at 494.

155. *Hecht v. Kane*, 20 Cal. Rptr. 2d 275, 283 (Cal. Ct. App. 1993) [hereinafter *Hecht I*]. The Court stated that the decedent had an interest, "in the nature of ownership" at the time of his death in the disposition of his sperm. *Id.* "Sperm which is stored by its provider with the intent that it be used for artificial insemination is thus unlike other human tissue because it is 'gametic material.'" *Id.* (citing *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1982)).

156. *Hecht I*, 20 Cal. Rptr. 2d at 283. Petitioner Hecht sought a peremptory writ of mandate/prohibition to vacate an order directing the decedent's estate to destroy the sperm in possession of the sperm bank. *Id.* at 276. The appellate court held that the trial court's order constituted an abuse of discretion and set aside the order. *Kane v. Hecht*, 44 Cal. Rptr. 2d 578, 584 (Cal. Ct. App. 1995) [hereinafter *Hecht II*].

157. *Hecht I*, 20 Cal. Rptr. 2d at 278.

158. *Id.* at 276.

159. *Id.* at 277.

160. *Id.* at 283. Kane appealed *Hecht I*'s vacate order in hopes that the subsequent appeal would stay the distribution of the sperm. The second appellate court held that the appeal would not stay the distribution of the sperm due to the risk of imminent injury or loss ordered the delivery of sperm. *Hecht II*, 44 Cal. Rptr. at 584.

[sperm] to special respect because of [its] potential for human life.”¹⁶¹ Analogously, the property value of cord blood stem cells lies in its potential for preserving human life. The parents who have banked their babies’ cord blood have every intention, as does a sperm donor, to retain control over the cells, and although they assign the care of those cells to a properly qualified bank, that bank is to act only as a custodian.

Given the nature of cord blood stem cells, courts should recognize a property interest in them, especially in light of the fact that the donor of the autologous stem cells does not waive the right to claim them. These cells belong to that donor and are not to be treated as mere refuse for later use by a medical institution.

B. The Regulatory Scheme Deprives a Person of Their Property

If cord blood is indeed property, in which the donor has a legitimate property interest, then the FDA promulgation of proposed cord blood regulations constitutes an improper deprivation of that property. The proposed cord blood regulations required that investigators and cord blood banking entities file an IND.¹⁶² Although an IND may be permitted to proceed within thirty days, this does not end the procedure.¹⁶³ A product that is required to proceed through the FDA regulatory mechanism imposed for new drugs is likely to be delayed in the regulatory system for up to fourteen years.¹⁶⁴ Fourteen years is far too long for a patient dying of a disease who could respond favorably to treatment with cord blood stem cell transplants.¹⁶⁵ Additionally, those entities that had the right to engage in cord blood cell banking would not have been able to release an individual’s cord blood sample without filing a supplement to the original IND.¹⁶⁶ The supplemental filing would have further extended the time period during which a person could not access their banked cord blood.¹⁶⁷

161. *Hecht I*, 20 Cal. Rptr. 2d at 283 (citing *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1982)).

162. CORD BLOOD DRAFT DOCUMENT, *supra* note 1.

163. See *supra* notes 21, 28, and accompanying text.

164. The Patent Term Restoration Act allows the patent life of a drug to be restored to account for the period it was bogged down in regulatory review at the FDA with an upper limit of 14 years. Patent Term Restoration Act, 35 U.S.C. § 156(c)(3) (1996).

165. According to a Tufts University study, the average total development phase for a new biological product from 1980 to 1994 was 61 months. MARILYN E. GOSSE, PH. D. ET AL., TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, U.S. APPROVAL BIOLOGICS: 1980 - 1994 (Mar. 22, 1996).

166. Investigational New Drug Application, 21 C.F.R. §§ 312.30, 312.31 (1996).

167. *Id.* at § 312.31.

Under these circumstances the government would not be taking the cord blood for governmental use,¹⁶⁸ but would be entirely denying access by promulgating regulations so restrictive that the *de facto* result would be to deny access to the donor's property. The Supreme Court has noted that

[c]ourts have held that the deprivation of the former owner rather than the accretion of a right or interest to the sovereign constitutes the taking. Government action short of acquisition of title or occupancy has been held, if its effects are so complete as to deprive the owner of all or most of his interest in the subject matter, to amount to a taking.¹⁶⁹

Such a denial of access may reasonably extend past the duration of the donor's life and constitute a complete taking of property.

Where the government has taken property by eliminating access, it must provide reasons and process sufficient to justify the deprivation of property. General principles of Due Process require the government to afford an individual:

(1) adequate notice of the charges or basis for government action; (2) a neutral decision-maker; (3) an opportunity to make an oral presentation to the decision-maker; (4) an opportunity to present evidence and witnesses to the decision-maker; (5) a chance to confront and cross-examine witnesses or evidence to be used against the individual; (6) the right to have an attorney present the individual's case to the decision maker; (7) a decision based on the record with a statement of reasons for the decision.¹⁷⁰

The proposed cord blood regulations did not afford individuals adequate notice of the intent to restrict access and imposed substantive requirements without adherence to the notice and comment rulemaking procedures.¹⁷¹ The proposed regulations also did not provide a mechanism by which the FDA could choose not to apply the rules, thus rendering any opportunity in which an individual could make an oral presentation to the

168. In order to accept this assertion, this Comment assumes that the government will not change the status of those samples that have already been banked for autologous use and deem them appropriate for allogeneic use. If the government were to utilize those samples for allogeneic use in association with a government program, then there would be a basis for saying that the government had performed a taking protected by the "Takings Clause" of the Constitution. U.S. CONST. amend. V.

169. *United States v. General Motors Corp.*, 323 U.S. 373, 378 (1945).

170. NOWAK & ROTUNDA, *supra* note 127, at 525.

171. Citizen's Petition, *supra* note 105, at 2.

decision-maker moot.¹⁷²

In order to satisfy the requirements of the Due Process clause, individualized determinations are necessary.¹⁷³ The proposed cord blood regulations, however, do not provide for an appeal to the decision-maker, presumably the FDA reviewers.¹⁷⁴ Individuals with cord blood stem cells would not be permitted access to their tissues if a cord blood bank was unable to satisfy the requirements imposed by FDA upon submission of an IND. In addition, if a cord blood bank released an individual's cord blood sample without satisfying the FDA requirements, it would be subject to the full panoply of FDA enforcement actions.¹⁷⁵

Finally, although the FDA required that the cord blood banks submit an IND, the cord blood banks did not have title to the samples.¹⁷⁶ Therefore, the IND requirement was inappropriate. The banks could not adequately represent the interests of the individual patients and an IND submitted by a bank or a hearing with the bank would not have constituted an opportunity for each patient to represent themselves. Thus, as the proposed cord blood regulations were constructed, the patients were denied due process.

Implementing the proposed cord blood regulations, prior to considering the comments that have been submitted to the docket would run contrary to the final requirements that the decision be based upon the record and include an explanation of the rationale behind it as required by the Administrative Procedure Act. The FDA has previously implemented interim rules without responding to comments, prompting one court to issue a preliminary injunction.¹⁷⁷ Nonetheless, the FDA implemented the proposed cord blood regulations, stating that "[i]n the interim, individuals wishing to pursue clinical investigations involving these products may submit investigational new drug applications. . . ."¹⁷⁸ This practice has already been condemned by one court, and by engaging in it, the FDA has, again, violated the individual's due process rights.¹⁷⁹

172. *Id.* at 9-10.

173. *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632 (1974).

174. Administrative Procedure Act, 5 U.S.C. § 556 (1994).

175. It is significant to note that the FDCA is a criminal statute with penalties including imprisonment; the Act also imposes civil liability, which in extreme cases can lead to debarment from involvement in the food and drug industry. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331 to 337 (1994).

176. See Cord Blood Registry Comments, *supra* note 98.

177. *Biodynamics v. United States*, Civ. No. JFM-95-919 (D. Md. Apr. 14, 1995).

178. CORD BLOOD DRAFT DOCUMENT, *supra* note 1, at 2.

179. *Biodynamics*, Civ. No. JFM-95-919 (D. Md. Apr. 14, 1995).

C. Propriety of FDA's Adoption of a Less Burdensome Alternative That Does Not Infringe Upon the Constitutional Interests of the Individuals While Maintaining Adequate Safeguards for the Protection of the Public Health

It is not appropriate to regulate cord blood stem cells as new drugs because they constitute a product that is never manipulated or altered; they are merely collected and stored. This type of regulation is overly burdensome because the patient never transfers ownership of the product — the product is merely held custodially by the cord blood stem cell centers. The center can never be in a position to file an investigational new drug application for a substance that it does not own outright, and thus, these circumstances render the proposed cord blood regulations inappropriate. Alternatively, the Cellular Tissue Framework is an appropriate mechanism to regulate cord blood stem cells.

A simple promulgation of guidelines for entities engaging in cord blood stem cell banking, and a recommendation that cord blood banks adhere to industry standards, may be sufficient to protect the public health without triggering the Fifth Amendment or causing an adverse impact on burgeoning technology.

The FDA's call for industry assistance in the development of cord blood standard is an excellent way for the FDA to take advantage of industry expertise. The industry has attempted to address the concerns voiced by the FDA by establishing standards for cord blood stem cell banking.¹⁸⁰ Cord Blood Associations have set standards with respect to transplantation,¹⁸¹ cell collection,¹⁸² and cell processing.¹⁸³ In addition, FDA concerns over false and misleading advertising claims and assertions may be adequately addressed by the requirements in the Cellular Tissue Framework or, alternatively, by the Federal Trade Commission.¹⁸⁴

180. FOUNDATION FOR ACCREDITATION OF HEMATOPOIETIC CELL THERAPY, *supra* note 12.

181. *See id.* at Part B (setting forth guidelines for program sizes, institutional review board requirements, data management, quality management, staffing requirements, inpatient unit requirements, and outpatient unit requirements).

182. *See id.* at Part C (setting forth guidelines for cell donor evaluation and selection, cell collection facilities, cell collection procedures).

183. *See id.* at Part D (setting forth guidelines for hematopoietic progenitor cell processing, cryopreservation, quality management, labels, storage, transportation, expirations, and record).

184. Industries regulated by the FDA are usually carved out of the FTC's jurisdiction, however, in some instances the FTC may take action if the practices constitute unfair or

VII. CONCLUSION

Cord blood stem cell research is in its infancy and has the potential for life-saving advancements if its growth is permitted to continue. Although it may be appropriate and necessary for the FDA to exert some control over cord blood stem cells, the FDA's proposed cord blood regulations are overly burdensome and inappropriate at these early stages of development and research. The adoption of less a burdensome scheme is beneficial to both the industry and the public health.

The theory that organs and tissues are personal property over which each person should have dispositional control is still in its formative years. Arguments for a property interest under the Constitution are compelling given the progress technology is making, and the issue will only continue to grow if it is not resolved now. Assuming *arguendo* that persons have a property interest in the tissues derived from a person's own body, government interference should be limited to the minimum level necessary to further the government's compelling state interests. The mechanism the FDA has proposed to regulate cord blood is overly burdensome and does not provide the individual with the necessary due process and, *de facto*, denies access to personal property. The FDA's adoption of the Cellular Tissue Framework as a regulatory scheme is a more fitting accommodation. It does not deprive citizens of access to cord blood stem cells intended for autologous transplantation, yet it protects the public health through less invasive means.

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deceptive trade practices. See generally Caswell O. Hobbs, *The FDA and the Federal Trade Commission*, in *FOOD AND DRUG LAW* 425 (Richard M. Cooper ed. 1991).